DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 5, 2015

Asclepion Laser Technologies GmbH
Ms. Antje Katzer
Regulatory Affairs Manager
Bruesseler Straße 10
07747 Jena, Thuringia
Germany

Re: K150140
Trade/Device Name: MCL 31 Dermablate
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 5, 2015
Received: May 8, 2015

Dear Ms. Katzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150140

Device Name

MCL 31 Dermablate

Indications for Use *(Describe)*

Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Asclepion Laser Technologies GmbH • Brüsseler Str. 10 • 07747 Jena • Germany

Traditional 510(k) SUMMARY

MCL 31 Dermablate

This Traditional 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH MCL 31 Dermablate is submitted in accordance with the requirements of 21 CFR 907.92 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant:	ASCLEPION LASER TECHNOLOGIES GmbH Bruesseler Str. 10 07747 Jena, Germany
Contact Person:	Mrs. Antje Katzer Product Management and International Regulatory Affairs
Phone: Fax: e-mail:	+49 3641 77 00 309 +49 3641 77 00 302 antje.katzer@asclepion.com
Preparation Date:	June 3, 2015
Device Name:	MCL 31 Dermablate
Common Name:	Er:YAG Laser

Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology 79-GEX 21 CFR 878.4810 Regulatory Class: Class II Product Codes: GEX
Equivalent Devices:	K081541 Dermablate Effect (Asclepion Laser Technologies) K101306 Fotona Dynamis Er:YAG Laser System (Fotona)
Device Description:	The MCL 31 Dermablate is a pulsed Er:YAG laser emitting a wavelength of 2940 nm. The system comprises a main console unit, a handpiece and is triggered by means of a footswitch. The MCL 31 is operated with a handpiece of larger spotsize. The system incorporates a suction unit for the safe removal of laser plume.
Intended Use:	The MCL 31 Dermablate laser system is intended for coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).

Summary of Technical Characteristics

	Proposed Modified Device	**Un-Modified Predicate Device**	**Un-Modified Predicate Device**
Name Manufacturer 510(k)	MCL 31 Dermablate Asclepion Laser Technologies	Dermablate Effect with Handpiece of larger spot size Asclepion Laser Technologies K081541	Dynamis Er:YAG Laser Fotona K101306
Intended Use (handpiece with larger spot size)	Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).	Coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery, oral surgery and ophthalmology (skin around the eyes).	Surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of lesions, complete or partial resection of internal organs, lesions, tissue ablation and vessel coagulation is necessary. Dermatology and Plastic Surgery, ENT Surgery, Oral/Maxillofacial Indications, Ophthalmology, Gynecology, General Surgery, Podiatry.
Laser medium wavelength	Er:YAG 2940 nm	Er:YAG 2940 nm	Er :YAG 2940 nm
Principle of interaction with skin	Ablation, Coagulation	Ablation, Coagulation	Ablation, Coagulation
Energy, max.	2,5 J	1,5 J	3,0 J
Power, max.	20 W	12 W	20 W
Frequency, max.	20 Hz	20 Hz	50 Hz
Spot size	1 – 12 mm	1 – 6 mm	0,3 – 12 mm
Fluence, max.	250 J/cm²	100 J/cm²	250 J/cm²
Pulsewidth	100 – 1000 µs	350 µs	100 – 1500 µs

Comparison to: The MCL 31 Dermablate laser system is substantially equivalent to the Dermablate Effect K081541 and the Fotona Dynamis Er:YAG laser K101306, with the same principles of operation, with similar parameter and the same indications for use. The fundamental scientific technology of the device is unchanged from the legally marketed predicates.

Nonclinical Performance Data: The MCL 31 Dermablate laser system is tested according to following standards:

ISO 14971:2009
DIN EN 60601-1:2006
DIN EN 60601-1-2:2007
DIN EN 60601-1-6:2007
DIN EN 60601-2-22:1996
DIN EN 60825-1:2007
DIN EN 62304:2006

Clinical Performance Data: None

Conclusion: The MCL 31 Dermablate laser system is another safe and effective device for Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).